

IN THE CLAIMS:

Claim 1 (Currently amended) A system that monitors respiratory events of a patient, the system comprising:

a physiological monitoring system;

means for removably affixing the physiological monitoring system to the patient's forehead; and

a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of the patient and produces corresponding pulse oximetry data signals;

a storage memory for storing the pulse oximetry data signals produced by said pulse oximetry sensor;

wherein said pulse oximetry sensor ~~[[is]]~~ and said storage memory are mounted on ~~[[a]]~~ the physiological monitoring system, eliminating all lead wires between the patient and the storage memory, and ~~that is affixed on said patient's head~~ such that the pulse oximetry sensor detects said ~~patient conditions~~ oxyhemoglobin saturation and pulse rate of the patient and produces said pulse oximetry data signals, thereby monitoring ~~[[said]]~~ the patient's condition.

Claim 2 (Currently amended) A system as defined in claim 1, ~~whereby~~ wherein the system monitors sleep related obstructive respiratory events of a patient during sleep.

Claim 3 (Currently amended) A system as defined in claim 1, further comprising a patient head position and movement sensor that produces a head position and movement signal that indicates position and movement of the patient's head ~~of said~~ patient.

Claim 4 (Currently amended) A system as defined in claim 1, further comprising means for producing a microphone that produces a sound data signal that indicates detected sounds produced by said patient.

Claim 5 (Cancelled)

Claim 6 (Currently amended) A system as defined in claim 1, further comprising a computing device that receives said pulse oximetry data signals and computes SpO₂ measurement from which a respiratory event may be identified.

Claim 7 (Currently amended) A system as defined in claim 1, further comprising a data transfer interface that communicates the pulse oximetry data signals from the system to an external computing device.

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Claim 8 (Original) A system as defined in claim 1, wherein said pulse oximetry sensor is a reflectance-type sensor.

Claim 9 (Currently amended) A system as defined in claim 1, further comprising a smart CPAP device that interfaces with and provides feedback to a neuromuscular stimulation device and that monitors efficacy of the neuromuscular stimulation device ~~records and stores time during which the smart CPAP device is on at a prescribed pressure, thereby monitoring patient compliance with a predetermined sleep regimen.~~


Claim 10 (Original) A system as defined in claim 1, further comprising a patient respiratory airflow detector.

Claim 11 (Original) A system as defined in claim 10, wherein the airflow detector comprises a nasal cannula or a pressure transducer.

Claim 12 (Original) A system as defined in claim 1, wherein said system interfaces with a neuromuscular stimulation device.

Claim 13 (Original) A system as defined in claim 12, further comprising a transmission coil wherein said transmission coil uses a power source of the system.

Claim 14 (Currently amended) A system as defined in claim 1, further comprising computing circuitry that receives said pulse oximetry data signals and identifies a respiratory event of the patient responsive to said pulse oximetry data signals,

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wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate a threshold level of oxyhemoglobin desaturation.

Claim 15 (Currently amended) A system as defined in claim 14, wherein values of the pulse oximetry data signal ~~values necessary to that~~ indicate the threshold level of oxyhemoglobin desaturation ~~and comprising a respiratory event of the patient~~ are variable.

Claim 16 (Currently amended) A system as defined in claim 14, whereby the threshold level of oxyhemoglobin desaturation ~~required to determine a respiratory event~~ is variable.

Claim 17 (Currently amended) A system as defined in claim 14, wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a respiratory event~~ is variable, and wherein the variable threshold level is based on a known ~~predetermined~~ relationship between the partial pressure of oxygen and oxyhemoglobin saturation.

Claim 18 (Currently amended) A system as defined in claim 14, wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a respiratory event~~ is variable, and the variable threshold level is based on at least one of the following criteria: peak oxyhemoglobin saturation, ~~[[or]]~~ nadir, ~~[[or]]~~ and peak oxyhemoglobin resaturation.

Claim 19 (Currently amended) A system as defined in claim 1, further including:
a computing system; and

a data transfer interface that communicates said ~~patient physiological~~ pulse oximetry data signals to the computing system;

wherein the computing system analyzes the ~~patient physiological~~ pulse oximetry data signals and computes time spent by the patient at each of a plurality of oxyhemoglobin saturation levels.

Claim 20 (Currently amended) A system as defined in claim 1, further
comprising including:

a patient head position and movement sensor that produces a head position and movement signal that indicates position and movement of the patient's head;

means for producing a sound data signal that indicates detected sounds produced by said patient;

a computing system; and

a data transfer interface that communicates ~~[[said]]~~ patient physiological data signals to the computing system, said patient physiological data signals including said pulse oximetry data signals, said head position and movement signal, and said sound data signal;

wherein the computing system analyzes the patient physiological data signals and identifies any abnormal respiratory events of the patient, classifying the analyzed data signals into one or more types of respiratory events.

Claim 21 (Original) A system as defined in claim 20, further including an expert system that summarizes any identified patient respiratory events and generates a patient report.

Claim 22 (Original) A system as defined in claim 20, further including an expert system that analyzes one or more patient physiological signals and detects patient arousals that can be used to confirm the respiratory event type classification.

Claim 23 (Currently amended) A system as defined in claim 20, further including an expert system that ~~receives the patient physiological data signals and~~ receives patient anthropomorphic and clinical information, receives said patient physiological data signals, analyzes the physiological data signals and patient clinical information against a database of sleep apnea risk data, and generates a sleep apnea risk evaluation report of the patient.

Claim 24 (Original) A system as defined in claim 1, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

Claim 25 (Currently amended) A system as defined in claim 1, wherein said means for removably affixing the physiological monitoring system ~~is affixed to the patient by~~ to the patient's forehead comprises an adjustable strap.

Claim 26 (Currently amended) A risk evaluation system that monitors sleep-related obstructive respiratory events of a patient and provides a patient risk evaluation, the system comprising:

61 (a) a physiological monitoring system that ~~is affixed on said patient's head and that~~ includes (i) a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of the patient and produces corresponding pulse oximetry data signals ~~to detect said patient conditions~~, thereby monitoring said patient's condition, ~~and includes~~ (ii) a storage memory that stores the pulse oximetry data signals produced by said pulse oximetry sensor, ~~and (iii) means for removably affixing the physiological monitoring system to the patient's forehead, whereby all lead wires between the patient and the storage means are eliminated;~~

(b) an expert system; and

(c) a data transfer interface that communicates said ~~patient physiological~~ pulse oximetry data signals to the expert system;

wherein the expert system receives and analyzes the ~~patient physiological~~ pulse oximetry data signals and generates a sleep apnea risk evaluation report of the patient.

Claim 27 (Currently amended) A system as defined in claim 26, wherein the expert system receives patient clinical information, and the expert system analyzes the patient anthropomorphic and clinical information is analyzed and compared and compares the patient clinical information to a database such that the patient is assigned into one of a plurality of discrete risk categories for sleep apnea.

Claim 28 (Currently amended) A system as defined in claim 26, further including:

a patient head position and movement sensor that detects position and movement of the head of said patient and produces corresponding head position and movement data signals.

Claim 29 (Currently amended) A system as defined in claim 26, further including: a microphone that produces a sound data signal that indicates detected sounds produced by said patient.

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Claim 30 (Currently amended) A system as defined in claim 26, further including a computing system that receives and analyzes the ~~patient physiological~~ pulse oximetry data signals and identifies any abnormal respiratory events of the patient, thereby producing ~~one or more~~ at least one secondary respiratory event signal that is ~~signals that are~~ provided to the expert system.

Claim 31 (Currently amended) A system as defined in claim 26, further comprising computing circuitry that receives said pulse oximetry data signals and identifies a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate a threshold level of oxyhemoglobin desaturation.

Claim 32 (Currently amended) A system as defined in claim 31 ~~claim 26~~, wherein values of the pulse oximetry data ~~signal values necessary to~~ signals that indicate oxyhemoglobin desaturation ~~and comprising a respiratory event of the patient~~ are variable.

Claim 33 (Currently amended) A system as defined in claim 31 ~~claim 26~~, ~~whereby~~ wherein the threshold level of oxyhemoglobin desaturation ~~required to~~ determine a respiratory event is variable.

Claim 34 (Currently amended) A system as defined in claim 31 ~~claim 26~~, wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a respiratory event~~ is variable, and wherein the variable threshold level is based on a known ~~predetermined~~ relationship between the partial pressure of oxygen and oxyhemoglobin saturation.

Claim 35 (Currently amended) A system as defined in claim 31 ~~claim 26~~, wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a respiratory event~~ is variable, and the variable threshold level is based on at least one of the following criteria: peak oxyhemoglobin saturation, ~~[[or]]~~ nadir, ~~[[or]]~~ and peak oxyhemoglobin resaturation.

Claim 36 (Currently amended) A physiological monitoring system comprising:
a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of a patient and produces corresponding pulse oximetry data signals;

a power source that provides electrical energy to the sensor and circuitry for operation; and

a storage memory that stores the pulse oximetry data signals produced by said pulse oximetry sensor; and

means for removably affixing said pulse oximetry sensor and circuitry, said power source, and said storage memory to the patient's forehead, and wherein said pulse oximetry sensor and circuitry, said power source, and said storage memory are affixed on said patient's body to detect the ~~patient conditions~~ oxyhemoglobin saturation and pulse rate and produce the corresponding data signals, provide electrical power, and store the data signals, respectively, thereby monitoring said patient's condition, and whereby all lead wires between the patient and the storage memory are eliminated.

Claim 37 (Currently amended) A system as defined in claim 36, further including:

a patient head position and movement sensor that produces a head position and movement data signal that indicates position and movement of the patient's head of said patient.

Claim 38 (Currently amended) A system as defined in claim 36, further including: a microphone that produces a sound data signal that indicates detected sounds produced by said patient.

Claim 39 (Original) A system as defined in claim 36, further comprising a data transfer interface that communicates data from the system to an external computer.

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Claim 40 (Currently amended) A system as defined in claim 36, further including an SpO₂ measuring circuit comprising multiple light sources, a photo diode that receives light from the light sources and produces a photo diode current ~~having an AC component and a DC component~~, a controlled current source that produces a substantially constant current, and an analog-to-digital converter that receives a difference input signal comprising the difference between the photo diode current and the constant current, the difference input signal having an AC component and a DC component, and produces the analog-to-digital converter producing a measurement current in response to said difference input signal, wherein the substantially constant current is selected such that the

difference input signal [[has an]] AC component [[that]] is substantially equal to [[its]]
the DC component.

Claim 41 (Currently amended) A system as defined in claim 36, further including a computing device that receives patient SpO₂ data produced by the pulse oximetry sensor and smooths the SpO₂ data, wherein the computing device smooths the SpO₂ data by performing ~~one or more~~ at least one of the following smoothing operations: (a) applying a moving window median filter that replaces a current data sample value with a median value selected from a predetermined number of data sample values, (b) applying a slew limitation filter that determines if two consecutive data sample values differ by more than a predetermined amount, and in response replaces a data sample value with a replacement value so as to limit the difference to no greater than the predetermined amount, and (c) applying an averaging technique that operates on multiple data sample values.

al Claim 42 (Original) A system as defined in claim 41, wherein the averaging technique comprises a first-order infinite impulse response (IIR) filter that operates on a current data sample value and a previous data sample value.

Claim 43 (Original) A system as defined in claim 41, wherein the computing device performs multiple smoothing operations and one or more of the smoothing

operations receives, as data input, smoothed data sample values produced by a different smoothing operation.

Claim 44 (Original) A system as defined in claim 36, further including a computing device that receives patient SpO₂ data produced by the pulse oximetry sensor and identifies SpO₂ data that indicates desaturation occurrences in accordance with rate of change of SpO₂ desaturation data.

Claim 45 (Original) A system as defined in claim 36, further including a computing device that receives patient SpO₂ data produced by the pulse oximetry sensor and identifies SpO₂ data that indicates desaturation related to abnormal respiratory events by identifying changes in patient physiological data that indicate patient arousal.

Claim 46 (Currently amended) A system as defined in claim 45, wherein the changes in patient physiological data include ~~one or more~~ at least one of changes in patient heart rate, patient position and movement, and patient produced sounds.

AI Claim 47 (Original) A system as defined in claim 36, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

Claim 48 (Currently amended) A system as defined in claim 36, wherein the means for removably affixing the physiological monitoring system ~~is affixed to the patient by~~ to the patient's forehead comprises an adjustable strap.

Claim 49 (Currently amended) A method of evaluating risk of sleep apnea in a patient, the method comprising:

attaching a physiological monitoring system to ~~[[the]]~~ a patient's forehead of the patient, wherein the physiological monitoring system includes (a) a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of the patient and produces corresponding pulse oximetry data signals, and (b) a storage memory that stores the pulse oximetry data signals produced by said pulse oximetry sensor, thereby eliminating all lead wires between the patient and the storage memory; and

providing the stored pulse oximetry data signals to an expert system that receives the stored pulse oximetry data signals, wherein the expert system performs an analysis and generates a sleep apnea risk evaluation report of the patient.

Q1 Claim 50 (Currently amended) A method as defined in claim 49, wherein the physiological monitoring system further includes a patient head position sensor that detects the position of the patient's head ~~of said patient~~ and produces corresponding head position data signals, and a microphone that detects snoring sounds produced by said patient and produces corresponding sound data signals, such that the physiological monitoring system thereby monitors said patient's condition.

Claim 51 (Currently amended) A method as defined in claim 49, further including:

analyzing the ~~patient physiological~~ pulse oximetry data signals and identifying any abnormal respiratory events of the patient, thereby producing one or more secondary respiratory event signals; and providing the secondary respiratory event signals to the expert system for analysis in generating the evaluation report.

Claim 52 (Currently amended) A method as defined in claim 49, further including the expert system receiving the ~~patient physiological~~ pulse oximetry data signals and utilizing a database to perform an analysis and generate the evaluation report of the patient.

Claim 53 (Currently amended) A method as defined in claim 52, wherein the expert system receives patient anthropomorphic and clinical information is analyzed and the expert system analyzes the patient clinical information using discriminant function analysis developed using information from a database.

Claim 54 (Currently amended) A method as defined in claim 52, wherein attaching the physiological monitoring system comprises attaching a system that further includes a patient head position and movement sensor that detects position and movement of the head of said patient and produces corresponding head position and movement data

signals, and a microphone that produces a sound data signal that indicates detected sounds produced by said patient, wherein said pulse oximetry data signals, said head position and movement data signals, and said sound data signal comprise patient physiological data signals.

Claim 55 (Currently amended) A method as defined in claim 54 ~~claim 52~~, further including providing the patient physiological data signals to a computing system that analyzes the patient physiological data signals and identifies any abnormal respiratory events of the patient, thereby producing one or more secondary respiratory event signals that are provided to the expert system.

Claim 56 (Currently amended) A method as defined in claim 52, further comprising providing said pulse oximetry data signals to computing circuitry that responds to the received pulse oximetry data signals by identifying a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate a threshold level of oxyhemoglobin desaturation.

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Claim 57 (Currently amended) A method as defined in claim 56 ~~claim 52~~, wherein values of the pulse oximetry data signals that ~~signal values necessary to~~ indicate the threshold level of oxyhemoglobin desaturation ~~and comprising a respiratory event of the patient~~ are variable.

Claim 58 (Currently amended) A method as defined in claim 56 ~~claim 52~~,
~~whereby~~ wherein the threshold level of oxyhemoglobin desaturation ~~required to~~
~~determine a respiratory event~~ is variable.

Claim 59 (Currently amended) A method as defined in claim 56 ~~claim 52~~,
wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a~~
~~respiratory event~~ is variable, and wherein the variable threshold level is based on a
known predetermined relationship between the partial pressure of oxygen and
oxyhemoglobin saturation.

Claim 60 (Currently amended) A method as defined in claim 56 ~~claim 52~~,
wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a~~
~~respiratory event~~ is variable, and the variable threshold level is based on at least one of
the following criteria: peak oxyhemoglobin saturation, [[or]] nadir, [[or]] and peak
oxyhemoglobin resaturation.

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Claim 61 (Currently amended) A method as defined in claim 49, further
including:

receiving light from multiple light sources of an SpO₂ measuring circuit at a photo
diode that produces a photo diode current ~~having an AC component and a DC~~
~~component~~;

producing a difference signal at an input of an analog-to-digital converter, wherein the difference signal comprises the difference between the photo diode current and a substantially constant current produced by a controlled current source, the difference input signal having an AC component and a DC component, such that the analog-to-digital converter ~~produces~~ producing a measurement current in response to the difference input signal, wherein the substantially constant current is selected such that the difference input signal ~~[[has an]]~~ AC component ~~[[that]]~~ is substantially equal to ~~[[its]]~~ the DC component.

Claim 62 (Currently amended) A method as defined in claim 49, further comprising: receiving patient SpO₂ data produced by the pulse oximetry sensor; and smoothing the SpO₂ data by performing ~~one or more~~ at least one of the following smoothing operations: (a) applying a moving window median filter that replaces a current data sample value with a median value selected from a predetermined number of data sample values, (b) applying a slew limitation filter that determines if two consecutive data sample values differ by more than a predetermined amount, and in response replaces a data sample value with a replacement value so as to limit the difference to no greater than the predetermined amount, and (c) applying an averaging technique that operates on multiple data sample values.

Claim 63 (Original) A method as defined in claim 62, wherein the averaging technique comprises a first-order infinite impulse response (IIR) filter that operates on a current data sample value and a previous data sample value.

Claim 64 (Currently amended) A method as defined in claim 62, wherein more than one of the multiple smoothing operations is performed, and ~~one or more~~ at least one of the smoothing operations receives, as data input, smoothed data sample values produced by a different smoothing operation.

Claim 65 (Original) A method as defined in claim 49, further including receiving patient SpO₂ data produced by the pulse oximetry sensor and identifying SpO₂ data that indicates desaturation occurrences in accordance with rate of change of SpO₂ desaturation data.

Claim 66 (Currently amended) A method as defined in claim 54 ~~claim 49~~, further including receiving patient SpO₂ data produced by the pulse oximetry sensor and identifying SpO₂ data that indicates desaturation related to abnormal respiratory events by identifying changes in patient physiological data that indicate patient arousal.

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Claim 67 (Currently amended) A method as defined in claim 66, wherein the changes in patient physiological data include ~~one or more~~ at least one of changes in patient heart rate, patient position and movement, and patient produced sounds.

Claim 68 (Original) A method as defined in claim 49, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

Claim 69 (Currently amended) A method as defined in claim 49, wherein the step of attaching the physiological monitoring system is affixed to the patient to the patient's forehead comprises affixing the physiological monitoring system to the patient's forehead by an adjustable strap.

Claim 70 (Currently amended) A physiological monitoring system comprising:

- a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of the patient and produces corresponding pulse oximetry data signals;
- a patient head movement sensor that produces a head movement and position data signal that indicates position and movement of the patient's head of said patient;
- a microphone that produces a sound data signal that indicates detected sounds produced by said patient;
- power means for providing electrical energy to said pulse oximetry sensor, said head movement sensor, and said microphone ~~the sensors~~ for operation; and
- memory means for storing the data signals produced by said pulse oximetry sensor, said patient head movement sensor, and said microphone; and

means for removably affixing said pulse oximetry sensor, said patient head movement sensor, said microphone, said power means and said memory means to the patient's forehead, wherein said sensors and power means are affixed on said patient's body to detect the patient conditions patient's oxyhemoglobin saturation, pulse rate, head movement and sounds, and produce the corresponding data signals, thereby monitoring said patient's condition, and whereby all lead wires between the patient and the memory means are eliminated.

Claim 71 (Currently amended) A system as defined in claim 70, further comprising computing circuitry that receives said pulse oximetry data signals and identifies a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate a threshold level of oxyhemoglobin desaturation.

Claim 72 (Currently amended) A system as defined in claim 71, wherein values of the pulse oximetry data signal values necessary to indicate oxyhemoglobin desaturation and comprising a respiratory event of the patient are variable.

61 Claim 73 (Currently amended) A system as defined in claim 71, whereby the threshold level of oxyhemoglobin desaturation required to determine a respiratory event is variable.

Claim 74 (Currently amended) A system as defined in claim 71, wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a respiratory event~~ is variable, and wherein the variable threshold level is based on a known ~~predetermined~~ relationship between the partial pressure of oxygen and oxyhemoglobin saturation.

Claim 75 (Currently amended) A system as defined in claim 71, wherein the threshold level of oxyhemoglobin desaturation ~~required to determine a respiratory event~~ is variable, and the variable threshold level is based on at least one of the following criteria: peak oxyhemoglobin saturation, or nadir, or peak oxyhemoglobin resaturation.

Claim 76 (Original) A system as defined in claim 71, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

Claim 77 (Currently amended) A system as defined in claim 71, wherein said means for affixing said pulse oximetry sensor, said patient head movement sensor, and said power means to the patient's forehead comprises the physiological monitoring system is affixed to the patient by an adjustable strap.

u Claim 78 (New) A method of evaluating risk of sleep apnea in a patient, comprising the steps of:
measuring a patient's oxyhemoglobin desaturation; and

comparing the patient's oxyhemoglobin desaturation with a threshold level of oxyhemoglobin desaturation required to determine a respiratory event, and wherein the threshold level of oxyhemoglobin desaturation is variable.

Claim 79 (New) The method of Claim 78, wherein the variable threshold level is based on a known relationship between partial pressure of oxygen and oxyhemoglobin saturation.

Claim 80 (New) The method of Claim 78, wherein the variable threshold level is based on at least one of the following criteria: peak oxyhemoglobin saturation, nadir, and peak oxyhemoglobin resaturation.

Claim 81 (New) The method of Claim 78, wherein the variable threshold level of oxyhemoglobin oxyhemoglobin desaturation is based at least in part on an automated detection of changes in patient snoring sounds, head movement, and pulse rate.

Claim 82 (New) A system for monitoring respiratory events of a patient, the system comprising:

61 a physiological monitoring system including a pulse oximetry sensor and circuitry, and storage means for storing physiological data, the pulse oximetry sensor and circuitry detecting oxyhemoglobin saturation and pulse rate of a patient and producing

corresponding pulse oximetry data signals, and the storage means storing a recording of the pulse oximetry signals; and

means for removably affixing said physiological monitoring system to the patient's forehead, whereby all lead wires between the patient and the means for storing are eliminated.

Claim 83 (New) The system of Claim 82, further comprising:

a power source that provides electrical energy to the pulse oximetry sensor and circuitry for operation; and

said means for storing comprises a storage memory that stores the pulse oximetry data signals produced by said pulse oximetry sensor;

wherein said power source and said storage memory are mounted on the physiological monitoring system.

Claim 84 (New) The system of Claim 82, wherein the means for removably affixing comprises an elastic strap and at least one foam pad mounted to said physiological monitoring system, said elastic strap and foam pad cooperating to apply a pressure of the pulse oximetry sensor against the patient's forehead.

Claim 85 (New) The system of Claim 84, wherein said pressure is optimized by adjusting the elastic strap and adjusting the thickness of said at least one foam pad.

Claim 86 (New) The system of Claim 85, further comprising means for measuring said pressure.

Claim 87 (New) The system of Claim 86, further comprising means for actively pressing the pulse oximetry sensor toward the patient's forehead.

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